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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,054		Peter Joseph Cassidy	080056-00020	3789

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 02/21/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,054	Applicant(s), Cassidy et al
	Examiner Maurie G. Baker, Ph.D.	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 32-108 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 32-108 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

<p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____</p>	<p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>
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DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1639 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Election/Restriction

1. The examiner noticed the following problem with the claims when preparing this Restriction Requirement. Claims 73 and 108 depend from claim 1, which is cancelled. It also appears that these claims are duplicates. It would assist in the examination of the case if this were corrected in the Reply to this action.
2. Please note that in the grouping of claims below, some claims appear in more than one group. This is because the claim contains more than one invention therein. Note PCT Rule 13.3 which requires that the determination of the existence of unity of invention be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim (emphasis added).
3. Also note that claims 74-90 are listed as the last “group” but in actuality contain within these claims a large number of separate inventions which lack unity. If claims 74-90 are elected, election of a single invention from within this group of claims is required as specifically set forth (see Groups LXXI., etc. below).

4. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention from the following groups to which the claims must be restricted.

- I. Claims 32, 33, 37, 38 and 44-46, drawn to compounds 4a-d, compounds 5a-d and methods of making the compounds.
- II. Claims 34, 39 and 43, drawn to compounds 6a-d and the deprotected versions thereof (compounds 13 and 18).
- III. Claims 35 and 40, drawn to compounds 7a-d.
- IV. Claims 36 and 41, drawn to compounds 8a-d.
- V. Claims 42 and 43, drawn to compound 10 and the deprotected version thereof (compound 11).
- VI. Claim 43, drawn to compound 12.
- VII. Claim 43, drawn to compound 14.
- VIII. Claim 43, drawn to compound 16 and the deprotected versions thereof (compounds 17 and 27).
- IX. Claim 43, drawn to compound 19.
- X. Claim 43, drawn to compound 21 and the deprotected version thereof (compound 22).
- XI. Claim 43, drawn to compounds 23a-d.
- XII. Claim 43, drawn to compound 25a-d.

- XIII. Claim 43, drawn to compound 26.
- XIV. Claim 43, drawn to compound 28.
- XV. Claim 43, drawn to compound 29.
- XVI. Claim 43, drawn to compound 30.
- XVII. Claim 43, drawn to compound 31.
- XVIII. Claim 43, drawn to compound 32.
- XIX. Claim 43, drawn to compound 33.
- XX. Claim 43, drawn to compound 34.
- XXI. Claim 43, drawn to compound 35a-c.
- XXII. Claim 43, drawn to compound 36.
- XXIII. Claim 43, drawn to compound 37.
- XXIV. Claim 43, drawn to compound 38.
- XXV. Claim 43, drawn to compound 43.
- XXVI. Claim 43, drawn to compound 44.
- XXVII. Claim 43, drawn to compound 45.
- XXVIII. Claim 43, drawn to compound 46.
- XXIX. Claims 44, 46 and 47, drawn to a first process for preparation of compounds 6a-d.
- XXX. Claims 44, 46 and 48, drawn to a process for preparation of compounds 7a-d.
- XXXI. Claims 44, 46 and 49, drawn to a first process for preparation of compounds 8a-d.
- XXXII. Claims 44, 46, 48 and 50, drawn to a second process for preparation of compounds 8a-d.

- XXXIII. Claims 44, 46, 48 and 51, drawn to a third process for preparation of compounds 8a-d.
- XXXIV. Claims 44, 46, 48, 50 and 52, drawn to a second process for preparation of compounds 6a-d.
- XXXV. Claims 44, 46, 48, 50, 53 and 54, drawn to a process for preparation of compounds 10 and 11.
- XXXVI. Claims 44, 46, 48, 50 and 53-55, drawn to a process for preparation of compound 12.
- XXXVII. Claims 44, 46, 48, 50 and 53-56, drawn to a first process for preparation of mimetic I(i).
- XXXVIII. Claims 44, 46, 48, 50, 53-55 and 57, drawn to a first process for preparation of mimetic I(i)a.
- XXXIX. Claims 44, 46, 47 and 58, drawn to a process for preparation of mimetic I(ii).
- XL. Claims 44, 46, 48, 50, 53 and 59, drawn to a process for preparation of compound 16.
- XLI. Claims 44, 46, 47 and 60, drawn to a first process for preparation of mimetic II(ii).
- XLII. Claims 44, 46, 47 and 61, drawn to a second process for preparation of mimetic II(ii).
- XLIII. Claims 44, 46 and 62, drawn to a process for preparation of mimetic II(iii).
- XLIV.
- XLV. Claims 44, 46 and 63, drawn to a process for preparation of mimetic II(iv).
- XLVI. Claims 44, 46, 48, 50, 53 and 64, drawn to a process for preparation of mimetic III(i).
- XLVII. Claims 44, 46, 48 and 65, drawn to a process for preparation of mimetic IV(i).
- XLVIII. Claims 44, 46 and 66, drawn to a first process for preparation of mimetic IV(ii).

- XLIX. Claims 44, 46 and 67, drawn to a second process for preparation of mimetic IV(ii).
- L. Claims 44, 46, 48, 50, 53, 54, 55, 57 and 68, drawn to a process for preparation of mimetic V.
- LI. Claims 44, 46, 48, 50, 53, 54, 55, 57 and 68, drawn to a process for preparation of mimetic VI.
- LII. Claim 69, drawn to a process for preparation of compound 54.
- LIII. Claims 69 and 70, drawn to a second process for preparation of mimetic I(i)a.
- LIV. Claims 69 and 71, drawn to a second process for preparation of compound 10.
- LV. Claim 72, drawn to a third process for preparation of mimetic I(i)a.
- LVI. Claim 73, drawn to a library of peptide mimetics. {see also Group LXX. below and paragraph 1. Unclear if claims 73 and 108 are duplicates.}

*** See “Group” LXXI. below for claims 74-90 (also see paragraph 3 above) ***

- LVII. Claims 91 and 92, drawn to compounds I(i)a.
- LVIII. Claims 93 and 94, drawn to compounds I(ii)a.
- LIX. Claims 95 and 96, drawn to compounds II(i)a.
- LX. Claims 97 and 98, drawn to compounds II(iii)a.
- LXI. Claim 99, drawn to compound III(i)a.
- LXII. Claim 100, drawn to compound III(iii)a.
- LXIII. Claim 101, drawn to compound IV(i)a.
- LXIV. Claim 102, drawn to compound IV(ii)a.
- LXV. Claim 103, drawn to compound V(i)a.

- LXVI. Claim 104, drawn to compound V(ii)a.
- LXVII. Claim 105, drawn to compound VI(i)a.
- LXVIII. Claim 106, drawn to compound VI(ii)a.
- LXIX. Claim 107, drawn to a fourth process for making of mimetic I(i)a.
- LXX. Claim 108, drawn to a library of peptide mimetics. {see also Group LVI. above and paragraph 1. Unclear if claims 73 and 108 are duplicates.}

Groups LXXI., etc.: Claims 74-90, drawn to a “general mimetic” of structure X. These claims contain a large number of independent and distinct inventions. If this group is selected than election of a single invention where the following groups are defined is required:

Q^1, Q^2, Q^3 and Q^4 (and Q^5 if present) must all be specifically defined

This means that each of the Q groups must be specifically set forth where the specific structure (cyclic, non-cyclic) is shown and all variable groups are defined therein. This should result in a single defined cyclic core structure showing all rings therein which is further functionalized by the R and M groups. See paragraph 2 above and the below explanation of why the groups lack unity, particularly paragraphs 11-14.

6. The inventions listed as Groups I – LXXI(and additional groups as defined above) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

7. It is noted that the “main invention” of the claims is defined as follows from 37 CFR 1.475 (emphasis added):

If multiple products, processes of manufacture or uses are claimed, *the first invention of the category first mentioned in the claims of the application* and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

Therefore, compounds 4a-d are the “main invention” of the claims.

8. The compounds 4a-d and 5a-d are related as intermediate and final products.

From MPEP 1850, unity of invention shall be considered to be present in the context of intermediate and final products where the following two conditions are fulfilled:

- (A) The intermediate and final products have the same essential structural element, in that:
 - (1) The basic chemical structures of the intermediate and the final products are the same, or
 - (2) The chemical structures of the two products are technically closely interrelated, the intermediate incorporating an essential structural element into the final product; and
- (B) The intermediate and final products are technically interrelated, this meaning that the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same essential structural element.

Therefore since compounds 4a-d and 5a-d are intermediate and final products and fulfill the criteria above *and* since compounds 4a-d are the “main invention” of the claims, the claims drawn to these compounds and to the methods of making them are included in Group I as per 37 CFR § 1.475 (b).

9. However, with respect to the rest of the claims, there is not a single inventive concept that links all of the claims. The compounds encompassed by the instant formulas do not all possess a common structure (no shared significant structural element) and each of the different structures would represent a different inventive concept.

10. Many of the claims do exhibit a “quasi”-relationship as intermediate and final products. However, the following from MPEP 1850 is noted (statements from MPEP in quotations). “It is possible to accept in a single international application different intermediate products used in different processes for the preparation of the final product, provided that they have the same essential structural element.” The instant application contains several different intermediates but they do not all have the same essential structural element. Also, “[t]he intermediate and final products shall not be separated, in the process leading from one to the other, by an intermediate which is not new.” Importantly, “[i]f the same international application claims different intermediates for different structural parts of the final product, unity shall not be regarded as being present between the intermediates.” The instant application does indeed claim different intermediates for different structural parts of the final product. For these reasons, the claims of Groups I – LVI lack unity.

11. Additionally see 37 CFR § 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited below (especially sections (c) – (e)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- A product and a process specially adapted for the manufacture of said product; or
- A product and process of use of said product; or
- A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- A process and an apparatus or means specifically designed for carrying out the said process; or
- A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

12. Groups LVII – LXXI (and additional groups as defined above) fall into categories

(c) and (d) above with respect to claims drawn to multiple products, processes of manufacture or uses and combinations of categories of invention.

13. Moreover, PCT Rule 13.2 states that unity of invention shall be fulfilled when

there is a technical relationship among those inventions involving one or more of the same or corresponding “special technical features”. It further defines “special technical

feature" as "those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art".

14. At least some of the inventions defined by Groups LVII – LXXI (and additional groups as defined above) are known in the art. See, for example, Kahn, M. Syn. Lett. 1993; on PTO-1449, Formulas 17, 18, 23 and 25-28 and Hanessian et al., Tetrahedron, 1997; on PTO-1449, page 12843.

15. For these reasons the Groups are deemed to lack unity of invention.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

18. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:00 to 6:30 and alternate Fridays.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306- 3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
February 12, 2003



MAURIE GARCIA BAKER, Ph.D.
PRIMARY EXAMINER



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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ART UNIT: 1639

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